Korean Clinical Practice Guidelines: Otitis Media in Children

- A summary report -

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Introduction

Considering the high prevalence and societal significance of AOM and OME in children, evidence-based guidelines for OM in the pediatric population have been developed in many countries and continue to be updated to reflect new evidence and changing social circumstances. As medical decisions should be based on the balance between risk and benefit based on existing evidence, national guidelines should reflect evidence from the particular region, and careful modification may be necessary considering the availability of medical facilities and social costs applied in each particular country.

The Korean Society of Otology launched a committee to develop clinical practice guidelines for pediatric OM in May 2009. The multidisciplinary committee consisted of seven members from the Korean Society of Otology and two members each recommended by the Korean Society of Pediatrics and the Korean Society of Family Medicine.

The recommendations in the guidelines are based on the best available published data identified by the committee members. The search covered materials published in English and Korean. Where qualified evidence was lacking, an expert consensus based on clinical experience was used. Each recommendation statement was graded using a modified system based on that used in the 2004 American Academy of Pediatrics guidelines for AOM, which consisted of four levels considering the quality of supporting evidence and clinical significance (Table 1).

Intended users of these guidelines include all physicians in Korea who care for children with AOM and OME, including otolaryngology, pediatrics, and family medicine specialists.
<table>
<thead>
<tr>
<th>Grade: statement</th>
<th>Definition</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Strong</td>
<td>The benefits of the recommended intervention clearly exceed the harm, and the quality of the evidence is excellent.</td>
<td>Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.</td>
</tr>
<tr>
<td>Recommendation</td>
<td>The benefits of the recommended intervention exceed the harm, but the quality of evidence is not as strong.</td>
<td>Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences.</td>
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<tr>
<td>B: Recommendation</td>
<td>The quality of evidence that exists is suspicious, or well-done studies show little clear advantage.</td>
<td>Clinicians should consider the option in their decision-making, and patient preference may play a substantial role.</td>
</tr>
<tr>
<td>C: Option</td>
<td>As pertinent published evidence is lacking, the anticipated balance of benefits and harm is unclear.</td>
<td>Clinicians should be alert to new published evidence that clarifies the balance of benefit vs. harm.</td>
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</table>
Guidelines for AOM in children

The practice guidelines are for children under 15 years old, including those under 6 months of age without other underlying diseases or any complications caused by AOM. Those in whom AOM complications were expected (i.e., Down's syndrome, craniofacial anomalies, including cleft palate, and those with immunodeficiencies, cochlear implant patients, patients with AOM that recurred within 30 days, AOM occurrence in a diseased state, or recurrent OM) were excluded; individual management is mandated for such patients.

Recommendation1. Diagnosis of AOM

Diagnosis of AOM is made based upon subjective symptoms and objective signs. Subjective symptoms refer to (1) acute onset and (2) middle ear or systemic symptoms due to acute inflammation. Objective signs include (1) tympanic membrane findings, including bulging, bullae, hyperemia, perforation with otorrhea, middle ear effusion (MEE), etc., and (2) tympanometry showing type B or C or identification of MEE via tympanocentesis. “Definite diagnosis” requires all of the subjective symptoms and one or more objective signs; “suspicious diagnosis” is defined as fulfilling all of the subjective symptoms but none of the objective signs (Table 2) (Recommendation grade: A).

Table 2. Diagnostic criteria for acute otitis media in children in Korea.

1. Subjective symptoms
   (1) Acute onset
   Abrupt onset of inflammatory symptoms clinically examined within 48 h and no longer than 3 weeks from onset
   (2) Middle ear or systemic symptoms due to acute inflammation
   Local middle ear symptoms, including otalgia and otorrhea
   Systemic symptoms, including crying, irritability, fever, or other symptoms due to the affected ear

2. Objective signs
   (1) Tympanic membrane findings
   Bulging, bullae, hyperemia, perforation with discharge, middle ear effusion
   (2) Other tests
   Tympanometry showing type B or C or tympanocentesis confirming the presence of middle ear effusion

Definite diagnosis: meets all of the subjective symptoms and one or more of the objective signs.
Suspicious diagnosis: meets all of the subjective symptoms and none of the objective signs.
Recommendation 2. Observation policy

The “observation policy” as initial management of AOM refers to watchful waiting for natural improvement for 48 to 72 h without use of antibacterial agents. However, in cases of 1) age under 6 months, 2) definite diagnosis of AOM in a patient under 24 months old, 3) severe AOM, 4) accompanying disease, such as tonsillitis, requiring administration of antibiotics, 5) inability to follow up after 48–72 h, and 6) recent antibiotic use, the “observation policy” is inappropriate for initial treatment (Table 3) (Recommendation grade: A).

Table 3. Indications for administering antibiotics initially without conservative therapy in pediatric acute otitis media

<table>
<thead>
<tr>
<th>1) &quot;Severe&quot; AOM*</th>
<th>2) Age younger than 6 months</th>
<th>3) 6–24 months old with definite diagnosis of AOM</th>
<th>4) Recent use of antibiotics</th>
<th>5) Presence of co-morbidities, such as tonsillitis, which require administration of antibiotics</th>
<th>6) Patients incapable of clinical follow-up after 2–3 days</th>
<th>7) Patients who had already undergone clinical monitoring for 2–3 days</th>
</tr>
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<tbody>
<tr>
<td>: Severe otalgia or irritability lasting longer than 24 h or fever higher than 38.5°C</td>
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</table>

Recommendation 3. First-line antibiotic therapy

We recommend high-dose amoxicillin (80–90 mg/kg/day) as the first-line antibiotic (Recommendation grade: A). However, if the patient is older than 24 months old with no recent antibiotic administration and has not been to a childcare facility, the standard dose of amoxicillin (40–50 mg/kg/day) is recommended as the first-line antibiotic. For severe AOM, high-dose amoxicillin/clavulanate (14:1) (80–90/6.4 mg/kg/day) is recommended as the first-line antibiotic, considering the possibility of β-lactamase-producing Haemophilus influenzae, Moraxella catarrhalis, and penicillin-resistant pneumococci as the causative organisms (Recommendation grade: A).

Recommendation 4. Second- and third-line antibiotic therapy

We recommend oral amoxicillin/clavulanate (14:1) 80–90/6.4 mg/kg/day as second-line antibiotic therapy. In cases in which second-line antibiotic therapy fails, parenteral administration of 50 mg/kg/day of ceftriaxone for 3 days is recommended as third-line antibiotic therapy (Table 4) (Recommendation grade: A). However, when the results of the antibacterial agent sensitivity test are available, the most appropriate
type of antibiotic can be chosen at any time after obtaining the result
(Recommendation grade: B).

Table 4. Recommended antibacterial agents for pediatric acute otitis media

<table>
<thead>
<tr>
<th>Grade</th>
<th>Antibiotic 1</th>
<th>Antibiotic 2</th>
<th>Antibiotic 3</th>
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<tbody>
<tr>
<td>1)</td>
<td>First-line</td>
<td>Second-line</td>
<td>Third-line</td>
</tr>
<tr>
<td></td>
<td>antibiotics</td>
<td>antibiotics</td>
<td>antibiotics</td>
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<tr>
<td></td>
<td>High-dose amoxicillin, 80–90 mg/kg/day</td>
<td>Amoxicillin/clavulanate (14:1) 80–90/6.4 mg/kg/day</td>
<td>Parenteral ceftriazone, 50 mg/kg/day × 3 days</td>
</tr>
<tr>
<td></td>
<td>Standard-dose amoxicillin, 40–50 mg/kg/day*</td>
<td>Amoxicillin/clavulanate (7:1) 40–50/6.4 mg/kg/day + amoxicillin 40 mg/kg/day</td>
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<tr>
<td></td>
<td>Alternative for penicillin allergy</td>
<td>Amoxicillin/clavulanate (4:1) 23–26/5.7 – 6.4 mg/kg/day + amoxicillin 57–64 mg/kg/day</td>
<td></td>
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<tr>
<td></td>
<td>Type I hypersensitivity: Macrolides</td>
<td>Alternative for penicillin allergy</td>
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<tr>
<td></td>
<td>Non-type I hypersensitivity: Cephalosporins</td>
<td>Type I hypersensitivity: Clindamycin</td>
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<tr>
<td></td>
<td>2) Second-line antibiotics†</td>
<td>Non-type I hypersensitivity: Parenteral ceftriaxone, 50 mg/kg/day × 3 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amoxicillin/clavulanate (14:1) 80–90/6.4 mg/kg/day</td>
<td>Amoxicillin/clavulanate (7:1) 40–50/6.4 mg/kg/day + amoxicillin 40 mg/kg/day</td>
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<td>Type I hypersensitivity: Clindamycin</td>
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<tr>
<td></td>
<td>Non-type I hypersensitivity: Parenteral ceftriaxone, 50 mg/kg/day × 3 days</td>
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<td></td>
</tr>
<tr>
<td>3)</td>
<td>Third-line antibiotic</td>
<td>Parenteral ceftriazone, 50 mg/kg/day × 3 days</td>
<td>Parenteral ceftriazone, 50 mg/kg/day × 3 days</td>
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<tr>
<td>4)</td>
<td>Antibiotic prescription and change can be done at any time necessary considering the bacterial culture and antibacterial agent sensitivity results, but it is desirable for the test to be conducted before the start of antibiotic treatment to increase positive results of the bacterial culture.</td>
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<td>5)</td>
<td>Summary of AOM treatment in children</td>
<td>Observation/Conservative therapy → First-line antibiotics → Second-line antibiotics → Third-line antibiotics</td>
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</tr>
<tr>
<td></td>
<td>In severe cases†, Second-line antibiotics → Third-line antibiotics</td>
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<td>In severe cases†, Second-line antibiotics → Third-line antibiotics</td>
</tr>
</tbody>
</table>

*: If older than 24 months and has no recent antibiotic administration and has no childcare facility attendance
†: Directly prescribe second-line antibiotics in severe AOM

Recommendation 5. Education to prevent AOM

When examining children diagnosed with AOM, it is recommended that the parent/caregiver be educated concerning the risk factors of AOM to prevent recurrent AOM (Recommendation grade: B).

Recommendation 6. Prevention: Pneumococcal conjugate vaccine

Injection of pneumococcal conjugate vaccine for prevention of AOM should be decided based on the benefits and risks, the clinician’s judgment, and parent’s/caregiver’s preferences (Recommendation grade: C). However, vaccination is recommended in patients with a high risk of meningitis following AOM, (i.e., children with/expecting a cochlear implant or with congenital inner ear anomalies) (Recommendation grade: A).
Recommendation 7. Documentation
When examining pediatric patients with suspected AOM, the physician should take the patient's history and document the following categories to achieve consistency in future examinations of the individual: (1) onset of AOM and symptoms of otalgia, otorrhea, fever, and irritability; (2) associated symptoms such as rhinorrhea, nasal obstruction, and sore throat; (3) past history of AOM treatment and other diseases; and (4) presence of high-risk factors (Recommendation grade: B).

Recommendation 8. Referral
Referral to other medical centers, including higher institutes for further evaluation and surgical treatment, is made by the primary clinician during the course of AOM in the following situations: (1) recurrent AOM; (2) tympanic membrane perforation lasting longer than 6 weeks; (3) mastoiditis or subperiosteal abscess; (4) labyrinthitis; (5) facial palsy; (6) spontaneous nystagmus; (7) central nervous system symptoms such as severe headache, high fever, or vomiting; or (8) suspicion of other intracranial complications. The primary clinician should provide the referral center with basic patient information and can request the results of medical examinations and treatment and also retransfer of the patient (Recommendation grade: B).

Recommendation 9. Complementary and alternative medicine
No recommendations for complementary and alternative medicine for treatment of AOM are made based on limited supporting data (Recommendation grade: D).
Figure 1. Algorithm for management of pediatric acute otitis media in Korea

Diagnosis of AOM

1. Subjective symptoms
   ① Acute onset
   ② Symptoms due to acute inflammation
2. Objective signs
   ① TM findings: drum bulging, bullae, hypanemia, discharge, effusion, etc.
   ② Tymanometry results of B or C type or tympanocentesis confirmed middle ear effusion

[Definite diagnosis] All of the subjective symptoms and one or more of the objective signs
[Suspicious diagnosis] All of the subjective symptoms and none of the objective signs

Antibiotic treatment

Illness severity, age, certainty of diagnosis

No

Patient factors

No

Observation policy without antibiotic agents (follow-up within 48-72h)

Yes

Presence of persistent acute symptoms

No

Education on risk factors

Yes

Severe illness

① Severe otalgia/irritability for 24 h
② Fever higher than 38.5°C

[Age and certainty of diagnosis]
① <6 months old
② >2 yrs old = definite diagnosis

① Antibiotics prior to the 1st visit
② Associated illness that necessitates antibiotics, such as acute tonsillitis, acute sinusitis, etc.
③ Unable to follow up after 2-3 days
Guidelines for OME in children

The clinical practice guidelines are intended to provide evidence-based recommendations to support clinical decisions regarding diagnosis, treatment, and prevention of OME in otherwise healthy Korean children under 15 years old. Application of these guidelines may be inappropriate for children simultaneously suffering from other co-existing disease(s) or at risk of complication associated with OM. An individualized approach to managing every problem in a comprehensive manner would be preferred in such cases.

Recommendation 1. Diagnosis of OME
OME is defined as the presence of middle ear fluid without acute signs or symptoms. Acute signs and symptoms associated with OM should be identified as absent by history-taking and physical examination. The presence of fluid in the middle ear can be determined by physical examination using electric otoscopy, pneumatic otoscopy, otoendoscopy, or otomicroscopy with support of tympanometry (Recommendation grade: A).

Recommendation 2. Hearing tests
Evaluation of hearing status in affected children is strongly recommended in these guidelines (Recommendation grade: A). Audiometric tests can be performed 1) at the time of diagnosis to measure hearing threshold, 2) any time during the follow-up period when presenting symptoms necessitate confirmation of hearing status, and 3) after a 3-month observation period for treatment planning. The appropriate method according to the developmental age of the particular child should be applied.

Recommendation 3. High-risk group
Criteria to define children at high risk in these guidelines are: 1) sensorineural hearing loss independent of OME; 2) uncorrectable visual impairment; 3) Down's syndrome or craniofacial anomalies; 4) cleft palate; 5) autism spectrum disorder or pervasive developmental disorder; 6) suspected or diagnosed speech and language delay; and 7) the developmental of other cognitive impairments (Recommendation grade: B).
Recommendation 4. Observation policy
The guidelines recommend that clinicians manage children with OME according to the observation policy for at least 3 months from onset, unless the child has any of the following exceptional factors. Exceptional cases that warrant earlier intervention include 1) children with high-risk factors as listed above, 2) when an irreversible change of the tympanic membrane is anticipated, and 3) presenting signs and symptoms suggesting complications, such as sudden aggravation of hearing loss or dizziness. Further treatment should be planned according to the status of the tympanic membrane, hearing status, and developmental status of language after a 3-month observation period (Recommendation grade: A).

Recommendation 5. Medication
The guidelines do not recommend medication such as antihistamines, decongestants, steroids and antibiotics of routine use for treating OME (Recommendation grade: A). In some cases, parents may be reluctant to agree to surgical intervention even in cases where early intervention is required, or may express anxiety over the lack of medication despite sufficient consultation. In such cases, antibiotic or antibiotic-steroid combination therapy can be administered for a short time (Recommendation grade: C).

Recommendation 6. Indications for surgical treatment
The decision for surgical intervention is made after 3 months of observation with evaluation of hearing. Exceptional cases for which surgical intervention should be considered earlier are 1) children at high risk and 2) children for whom changes in the tympanic membrane are anticipated to progress to irreversible changes (Recommendation grade: A). For otherwise healthy children, hearing status is a key factor determining whether surgery should be performed. In bilaterally affected cases, surgical intervention is recommended if hearing level (HL) in the better ear is 40-dB HL or above. If hearing level is between 20- and 40-dB HL, the guidelines recommend making a decision considering the medical/developmental status of child and parental preference (Recommendation grade: A). In unilaterally affected children, physicians may consider surgery, taking the duration of disease, hearing status, and parental preference into consideration (Recommendation grade: C).
**Recommendation 7. Choice of surgical intervention**

Ventilation tube insertion is the preferred initial procedure when a child becomes a surgical candidate. Adenoidectomy and/or tonsillectomy may be performed simultaneously if the status of the adenoid and the pharyngeal tonsil indicates these additional procedures. Adenoidectomy may be performed with ventilation tube insertion in recurrent cases for repeated surgical intervention *(Recommendation grade: B)*.

**Recommendation 8. Other recommendations for OME**

When a clinician provides medical care for a child with OME, the guidelines recommend providing clear information about the etiology and natural course of the disease as well as treatment options to the patient and his/her parent or caregiver *(Recommendation grade: B)*. It is good practice for medical professionals to provide not only verbal information but also written documents for patients and their family members.

To facilitate continuing care, documentation of detailed history is recommended including details of the onset of OME, symptoms derived from OME, associated symptoms, past medical history, and presence of high-risk factors of the child *(Recommendation grade: B)*. Primary clinicians may refer the patient to other medical centers, including higher referral centers for audiometric/developmental evaluation and surgical intervention. The primary clinician should provide the referred center with basic patient information and can request the results of medical examinations and treatment and also retransfer of the patient *(Recommendation grade: B)*.

No recommendations for complementary and alternative medicine for treatment of OME are made based on limited supporting data *(Recommendation grade: D)*.
Figure 2. Algorithm for management of pediatric otitis media with effusion in Korea